IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

CATHY KING, an individual, and STEVE KING, an individual, **Plaintiffs,** **vs.** **PFIZER, INC., WYETH, LLC, WYETH PHARMACEUTICALS, INC., SCHWARZ PHARMA, INC., PLIVA, INC., and JOHN DOE PHARMACEUTICAL COMPANIES 1-40,** **Defendants.**	**8:13CV290** **MEMORANDUM AND ORDER**

This matter is before the Court on the Motion for Summary Judgment submitted by Defendants Pfizer Inc. ("Pfizer"), Wyeth LLC, and Wyeth Pharmaceuticals Inc. (collectively "Wyeth"), and Schwarz Pharma, Inc. n/k/a UCB, Inc. ("Schwarz") (Filing No. 112, hereafter the "Motion"). Pfizer, Wyeth, and Schwarz (collectively "Defendants") all move for summary judgment on issues of statutes of limitations and repose.

Because the Court concludes that the Plaintiffs' claims are barred by Nebraska's applicable statute of repose, the Court will grant Defendants' Motion (Filing No. 112).

FACTUAL AND PROCEDURAL HISTORY

The following facts are those presented in the Defendants' Memorandum of Law in Support of Motion for Summary Judgment (Filing No. 113), supported by pinpoint citations to the evidentiary record (Filing No. 114) in compliance with NECivR 56.1(a), and not contested by Plaintiffs in their Brief and evidentiary submissions (Filing No. 164). *See* NECivR 56.1(b). Also included are some additional relevant facts presented in Plaintiffs' Brief, supported by pinpoint citations to the evidentiary record, and not

contested in Defendants' Reply Brief (Filing No. 166).[1] For purposes of the pending Motion, all facts are viewed in a light most favorable to Plaintiffs.

The Defendants are Delaware corporations with their principal places of business in New Jersey (Wyeth), New York (Pfizer), and Georgia (Schwartz). The Defendants are engaged in the business of manufacturing and distributing pharmaceuticals.

Plaintiff Cathy King ("Mrs. King") was at all relevant times a Nebraska resident. She was first prescribed the pharmaceutical product known as Reglan®, or its generic bioequivalent metoclopramide, in 1988 for treatment of gastrointestinal conditions. Injectable Reglan® was administered to her on several occasions between September 1992 and May 1994. She stopped taking Reglan®/metoclopramide in or about 1995, but resumed again in or about May 2000, then stopped in late 2005.

Since the mid-1980s, before Mrs. King began ingesting Reglan®/metoclopramide, the product labeling for Reglan® warned that tardive dyskinesia, "a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with metoclopramide" and "[b]oth the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose." (Filing No. 114-5 at ECF 3.)

From 1989 to 1991, Mrs. King began to experience involuntary facial movements, rapid eye blinking, teeth grinding, and tongue biting. She and her husband, Plaintiff Steve King ("Mr. King"), were aware that she suffered from movement

[1] The Court's Local Rules do not require the non-moving party to submit an "additional statement of material facts," nor do they address whether a moving party must respond to additional statements of material facts. Accordingly, the Court, in its discretion, has considered Plaintiffs' additional facts to the extent they are helpful to the Court's analysis.

disorders in the 1990s. By January 2001, Mrs. King's involuntary movements occurred more often, and her symptoms included lip-smacking. In February 2001, a treating physician noted that Mrs. King experienced rhythmic movements of the mouth and tongue. When Mrs. King was admitted to a hospital in March of 2001, staff observed and noted her lip-smacking. By February 2002, her symptoms included lip-smacking, teeth grinding, facial twitching, rapid blinking, and tongue movement. In February 2006, a physician's assistant noted that Mrs. King had tongue-thrusting, lip-licking, and abnormal neck movements. In July 2006, one physician observed Mrs. King's automatic movements of the mouth, and another physician noted that Mrs. King exhibited symptoms like tardive dyskinesia. In August 2006, a physician's assistant noted that Mrs. King had rolling, parkinsonian type movements of the head and neck. In September 2006, Mrs. King began to see a new physician's assistant for psychiatric symptoms, including hallucinations, anxiety, and depression. That physician's assistant noted that Mrs. King had many tics, including head movement and lip-smacking, and recommended that she see a neurologist. Mrs. King declined. On at least five subsequent visits in 2006, and three visits in early 2007, that physician's assistant noted that Mrs. King continued to experience dyskinesia. On December 12, 2006, two physicians noted that Mrs. King had what appeared to be "worsening tardive dyskinesia," and recommended she discuss the condition with a psychiatrist. In June 2007, Mrs. King's medical providers again noted her dyskinesia, including increased tongue movements and more tics. In September 2007, a physician noted Mrs. King's spontaneous mouth movements, suggestive of side effects of medication. In December

2008, a treating physician noted Mrs. King's involuntary jerking of extremities and lip-smacking.

In February 2011, Mr. King saw a television advertisement discussing a link between Reglan®/metoclopramide and tardive dyskinesia. In March 2011, Mrs. King saw a physician about her movement disorder and said the movements began when she was taking Reglan®. In August 2011, the physician diagnosed Mrs. King with tardive dyskinesia.

On August 7, 2013, Plaintiffs filed this action in the District Court of Lancaster County, Nebraska. Defendants removed the action to this Court, based on the Court's diversity jurisdiction.

In their Complaint (Filing No. 1-13), Plaintiffs allege that Wyeth's corporate predecessors developed Reglan® and marketed it throughout the 1980s; that Wyeth continued to manufacture, distribute, and sell Reglan® after certain corporate mergers in 1989; that Wyeth sold its rights to Reglan® tablets to Schwartz in December 2001; that Pfizer acquired Wyeth in 2009; and that Defendants Pliva, Inc. ("Pliva"), and John Doe Pharmaceutical Companies 1-40 ("John Does"), manufactured, distributed, and sold generic versions of metoclopramide since 1984, using the same warning labels or package inserts as Reglen®.

Plaintiffs' First Cause of Action concerns personal injury to Mrs. King, and presents five remaining theories of recovery[2]: (1) product liability, asserted against Wyeth, Schwarz, Pliva, and John Does, (2) conscious misrepresentation involving

[2] Plaintiffs' sixth theory of recovery was asserted against Defendant Monte Scott, M.D., who was dismissed from this action. See Findings and Recommendation at Filing No. 30, and Memorandum and Order at Filing No. 31.

physical harm, asserted against Wyeth, (3) negligent misrepresentation, asserted against Wyeth, (4) common law fraud and fraudulent concealment, asserted against Wyeth, and (5) negligent failure to provide adequate warnings for a prescription drug, asserted against Schwarz. Plaintiffs' Second Cause of Action concerns Mr. King's loss of consortium.

STANDARD OF REVIEW

"Summary judgment is appropriate when the record, viewed in the light most favorable to the non-moving party, demonstrates there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." *Gage v. HSM Elec. Prot. Servs., Inc.*, 655 F.3d 821, 825 (8th Cir. 2011) (citing Fed. R. Civ. P. 56(c)). The court will view "all facts in the light most favorable to the non-moving party and mak[e] all reasonable inferences in [that party's] favor." *Schmidt v. Des Moines Pub. Sch*., 655 F.3d 811, 819 (8th Cir 2011). "[W]here the nonmoving party will bear the burden of proof at trial on a dispositive issue . . . Rule 56(e) permits a proper summary judgment motion to be opposed by any of the kinds of evidentiary materials listed in Rule 56(c), except the mere pleadings themselves." *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986). The moving party need not negate the nonmoving party's claims by showing "the absence of a genuine issue of material fact." *Id*. at 325. Instead, "the burden on the moving party may be discharged by 'showing' . . . that there is an absence of evidence to support the nonmoving party's case." *Id*.

In response to the movant's showing, the nonmoving party's burden is to produce specific facts demonstrating "'a genuine issue of material fact' such that [its] claim should proceed to trial." *Nitro Distrib., Inc. v. Alticor, Inc.*, 565 F.3d 417, 422 (8th Cir.

2009) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 586 (1986)). The nonmoving party "'must do more than simply show that there is some metaphysical doubt as to the material facts,' and must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Torgerson v. City of Rochester*, 643 F.3d 1031, 1042 (8th Cir.) (quoting *Matsushita*, 475 U.S. at 586-87)), cert. denied, 132 S. Ct. 513 (2011). "'[T]he mere existence of some alleged factual dispute between the parties'" will not defeat an otherwise properly supported motion for summary judgment. Quinn v. St. Louis Cnty., 653 F.3d 745, 751 (8th Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 247-48 (1986)).

In other words, in deciding "a motion for summary judgment, 'facts must be viewed in the light most favorable to the nonmoving party only if there is a "genuine" dispute as to those facts.'" *Ricci v. DeStefano*, 557 U.S. 557, 586 (2009) (quoting *Scott v. Harris,* 550 U.S. 372, 380 (2007)). Otherwise, where the Court finds that "the record taken as a whole could not lead a rational trier of fact to find for the non-moving party"–where there is no "'genuine issue for trial'"–summary judgment is appropriate. *Matsushita,* 475 U.S. at 587 (quoting *First Nat'l Bank of Ariz. v. Cities Serv. Co*., 391 U.S. 253, 289 (1968)).

DISCUSSION

Defendants assert that Plaintiffs' theories of recovery are all product liability claims, barred by Nebraska's statute of limitations, and by the Nebraska statute of repose in effect when Mrs. King began taking Reglan®/metoclopramide.

I. The Nature of Plaintiffs' Theories of Recovery

Nebraska law defines a "product liability action" as

> any action brought against a manufacturer, seller, or lessor of a product, regardless of the substantive legal theory or theories upon which the action is brought, for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formulation, installation, preparation, assembly, testing, packaging, or labeling of any product, or the failure to warn or protect against a danger or hazard in the use, misuse, or intended us of any product, or the failure to provide proper instructions for the use of any product.

Neb. Rev. Stat. §25–21,180 (Reissue 2008).

Regardless of how a plaintiff may label a claim, if it fits the definition set out in § 25-21,180, it is a product liability action. *See, e.g., Groth v. Sandoz, Inc.*, 601 F. Supp. 453, 455 (D. Neb. 1984) (holding that the plaintiff's suit was a product-liability action even where "Plaintiff designates her causes of action as negligence, strict liability, [and] warranty") (citing *Morris v. Chrysler Corp.*, 303 N.W.2d 500 (Neb. 1981)); *Peterson v. Fuller Co.*, 807 F.2d 151, 152 (8th Cir. 1986), *cited with approval by Farber v. Lok-N-Logs, Inc.*, 701 N.W.2d 368, 375, 377 (Neb. 2005) (affirming where "[t]he district court determined that plaintiffs' actions were 'product liability' actions within the terms of" Neb. Rev. Stat. Ann. § 25-21,180 even where plaintiffs labeled their claims as "defective manufacture, installation, design, and warning"); *In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig.*, 756 F.3d 917, 948 (6th Cir. 2014) (interpreting § 25-21,180 broadly to mean that "claims against a product manufacturer for injuries allegedly caused through use of a product are 'product liability actions' under the statute, no matter the theory alleged.") (citation omitted); *BNSF Ry. Co. v. L.B. Foster Co.,* 917 F.Supp.2d 959, 966–67 (D. Neb. 2013) ("the characterization of an action is 'determined by the nature of the complaint, not by the form of the pleadings, and consideration must be given to the facts which constitute the cause of action.'" (quoting *Thomas v. Countryside of Hastings, Inc.,* 524 N.W.2d 311, 313 (Neb. 1994)).

Here, the Plaintiffs' theories of recovery all are essentially product liability claims, as defined in § 25-21,180. Plaintiffs admit in their brief that "[a]ll of Mrs. King's claims (or "theories of recovery") do rest, in part, on allegations that she sustained injuries as a physical result of toxic cumulative over-exposure to the drug substance metoclopramide . . . in the course of consuming various metoclopramide products, as they were dispensed to her." (Plaintiffs' Brief, Filing No. 164 at ECF 12.) Each of Plaintiffs' claims essentially seeks damages against a product manufacturer for injuries allegedly caused through use of Reglan. Accordingly, all of Plaintiffs' theories of recovery are product liability claims and are subject to Nebraska's applicable statute of limitations and statute of repose.

II. Nebraska's Statute of Limitations for Product Liability Actions

Defendants argue that Plaintiffs' claims are barred by Nebraska's products liability statute of limitations, Neb. Rev. Stat. § 25-224(1) (Reissue 2008), that provides: "All products liability actions . . . shall be commenced within four years next after the date on which the death, injury, or damage complained of occurs." Defendants note that the period of limitation "begins to run when a potential plaintiff discovers, or in the exercise of reasonable diligence should discover, the existence of the injury[.]" *Shlien v. Bd. of Regents, Univ. of Neb*., 640 N.W.2d 643, 651 (Neb. 2002). Defendants acknowledge that the question of when the statute of limitations begins to run is generally a question of fact, but Defendants argue that the relevant facts are undisputed in this case and so the question is one of law to be resolved by the Court.

Plaintiffs acknowledge that Mrs. King knew she had certain symptoms, disorders, or conditions in the 1990s, ultimately diagnosed as tardive dyskinesia by the end of

2006. Plaintiffs contend, however, that they were not aware that Mrs. King's disease was an "injury" or "damage" with an external cause, until Mr. King viewed the television advertisement in February 2011, suggesting the link between Reglan®/metoclopramide and tardive dyskinesia.

While the Defendants point to evidence suggesting that Mrs. King knew or should have known by early 2007 that her symptoms were associated with past ingestion of antiemetic medication, a genuine issue of material fact remains as to when Mrs. King knew, or with reasonable diligence should have known, that her condition was an "injury" or "damage" with an external cause. Accordingly, Defendants' Motion will be denied as to the statute of limitations.

III. Nebraska's Applicable Statute of Repose

From 1981 to 2001, Nebraska's products liability statute of repose provided that "any product liability action . . . shall be commenced within ten years after the date when the product which allegedly caused the personal injury, death, or damage was first sold or leased for use or consumption."[3] Neb. Rev. Stat. § 25-224(2) (Reissue 1995). The phrase "first sold . . . for use or consumption" refers to the date the product was relinquished to the ultimate first user or consumer. *Witherspoon v. Sides Constr. Co.,* 362 N.W.2d 35, 41 (Neb. 1985).

The Plaintiffs acknowledge that § 25-224(2) called for the commencement of their product liability action within ten years after the Reglan®/metoclopramide product was first sold or dispensed to Mrs. King, and that "literal application" of § 25-224(2)

[3] In 2001, section 25-224(2) "was amended to provide a distinction between products manufactured inside Nebraska and products manufactured outside Nebraska with respect to the application of the statute of repose." *Farber*, 701 N.W.2d at 374.

"would extinguish any such cause of action that she then had." (*See* Plaintiffs' Brief, Filing No. 164 at 37 (citing *Givens v. Anchor Packing, Inc*., 466 N.W.2d 771 (Neb. 1991)).) Plaintiffs assert, however, that the Defendants wrongfully concealed material facts, causing the Plaintiffs to delay the filing of their suit beyond the statutory time limit, and the Defendants should be estopped from asserting the statute of repose defense. (*Id.* (citing *MacMillen v. AH Robins Co., Inc.,* 348 N.W.2d 869, 871 (Neb. 1984); *Groth,* 601 F. Supp. at 457.) Plaintiffs also contend that Mrs. King's cause of action should begin to run anew with each Reglan®/metoclopramide prescription dispensed to Mrs. King. (*See* Plaintiffs' Brief, Filing No. 164 at 46-49.)

Under the theory of equitable estoppel, a defendant "fraudulently concealing a product's dangers [is] estopped from asserting the product liability statute of repose." *Givens,* 466 N.W.2d at 774. "To establish fraudulent concealment, . . . a plaintiff must show that: (1) 'he or she exercised due diligence to discover his or her cause of action' before the relevant time period expired; and (2) the defendant concealed 'any facts which would have put [the plaintiff] on notice of any cause of action.'" *Stuart v. Am. Cyanamid Co.*, 158 F.3d 622, 628 (2d Cir. 1998) (quoting *Upah v. Ancona Bros. Co.,* 521 N.W.2d 895, 902 (Neb. 1994)). "When the 'means of knowledge [are] at hand to put the plaintiff on inquiry of any cause of action she might have had against the defendants,' a plaintiff cannot claim fraudulent concealment." *Stuart*, 158 F.3d at 628 (quoting *Upah,* 521 N.W.2d at 905).

The Plaintiffs refer to their Complaint, and its allegations, in support of their contention that Defendants engaged in conduct "aimed at misinforming doctors concerning the risks of tardive dyskinesia" and maintained a "fiction of comparative

safety, despite . . . knowledge that those claims for the safety of the drug . . . were false or reckless." (Plaintiffs' Brief, Filing No. 164 at 38.) More specifically, Plaintiffs allege that Defendants "failed to alert the FDA to published, peer-reviewed research" indicating that Reglan®/metoclopramide, prescribed on a prolonged basis, could have greater risks than earlier anticipated. (*Id.* at 39.) Plaintiffs state that Defendants "do not demonstrate that the plaintiff *cannot* prove her allegations, or negate (or even dispute) those allegations with evidence—as Rule 56 would require." (*Id.* at 39, n.16 (emphasis in original).)

In essence, the Plaintiffs argue that *if* the Defendants had provided more comprehensive data to the FDA, and *if* the labeling on Reglan®/metoclopramide had included more warnings, Mrs. King's treating physicians might not have prescribed Reglan®/metoclopramide to her for such prolonged periods. While there may be a genuine issue of material fact as to whether the Plaintiffs exercised due diligence to discover their causes of action before the relevant time period expired, there is no evidence in the record from which a reasonable jury could infer that Defendants concealed facts that would have put Plaintiffs on notice of any cause of action before the Nebraska statute of repose barred their claims.

With respect to Plaintiffs' argument that Mrs. King's cause of action should begin to run anew with each Reglan®/metoclopramide prescription, *Groth*, a factually similar case provides guidance. The plaintiff in *Groth* began taking a pharmaceutical in January 1971, continuing through January 1980. In February 1981, she was diagnosed with end-stage renal failure. She commenced her action against the pharmaceutical manufacturer in August 1983. First, the Court rejected the plaintiff's contention that §

25-224(2) was unconstitutional. *Groth*, 601 F. Supp. at 455. Second, the Court found that the plaintiff's claims based on negligence, strict liability in tort, and breach of express and implied warranties, clearly were in the nature of product liability actions under Nebraska law. *Id.* Third, the Court concluded that plaintiff's claim of fraud was one based on allegations of misrepresentation and failure to warn—"the same as those generally pled in product liability actions" and "grounded in product liability." *Id.* at 456. Finally, the Court noted that plaintiff's argument that the defendant's fraudulent concealment should cause the defendant to be estopped from using the statute of repose as a defense was "unsupported by the record." *Id*. Accordingly, the Court granted the drug manufacturer's motion for summary judgment, finding all the plaintiff's claims to be barred by Nebraska's product liability statute of repose, § 25-224(2). Of note, the Court did not re-set the limitations period with each new prescription or consumption of the pharmaceutical, nor would such an approach be consistent with the clear language of § 25-224(2) and *Witherspoon,* 362 N.W.2d at 41.

As in *Groth*, the Plaintiffs' claims of fraud, and fraudulent concealment, are essentially claims of misrepresentation or failure to warn and are grounded in product liability. The statute of repose in § 25-224(2) is "a substantive right" conferred by the legislature on products liability defendants and, once vested by the passage of the 10-year period after the date when the product was first sold for use or consumption, the right cannot be removed by legislation or court action. *Farber,* 701 N.W.2d at 377-78. Passage of the 10-year period, following Mrs. King's first Reglan®/metoclopramide prescription in 1988, vested the Defendants with a substantive right under § 25-224(2)

as it existed prior to 2001, and the Plaintiffs' actions are barred by Nebraska's applicable statute of repose.

CONCLUSION

The Plaintiffs' claims are all essentially product liability claims, as defined in Neb. Rev. Stat. § 25-21,180, and they are subject to Nebraska's applicable 10-year statute of repose which began to run in 1988. The Plaintiffs' action was not timely filed and her claims will be dismissed, with prejudice.

IT IS ORDERED:

1. The Motion for Summary Judgment (Filing No. 112) submitted by Defendants Pfizer Inc., Wyeth LLC, Wyeth Pharmaceuticals Inc., and Schwarz Pharma, Inc., is granted in part as follows:

> The Plaintiffs' claims are barred by Nebraska's applicable statute of repose, Neb. Rev. Stat. § 25-244(2) (Reissue 1995),

And the Motion is otherwise denied;

2. The Plaintiffs' Complaint is dismissed, with prejudice, as to all Defendants;

3. All other pending Motions in this action are denied as moot;

4. The parties will bear their own costs and attorney fees, and

5. A separate Judgment will be issued.

Dated this 19th day of August, 2016.

BY THE COURT:

s/Laurie Smith Camp
Chief United States District Judge